

## Food and Drug Administration, HHS

## § 520.1044a

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 6463, Feb. 12, 2007]

### § 520.1010 Furosemide.

(a) *Specifications.* (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use of dosage forms and strengths listed in paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000061 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(3) Nos. 000859 and 058829 for use of syrup in paragraph (a)(4) of this section for conditions of use in paragraph (d)(2)(i) and (d)(2)(ii)(A) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount.* 1 to 2 mg per pound (lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) *Indications for use.* For treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) *Dogs*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use*—(A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) *Cats*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use.* For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

[66 FR 47960, Sept. 17, 2001, as amended at 69 FR 74419, Dec. 14, 2004; 70 FR 50182, Aug. 26, 2005; 70 FR 76396, Dec. 27, 2005; 74 FR 61516, Nov. 25, 2009; 78 FR 17596, Mar. 22, 2013]

### § 520.1044 Gentamicin sulfate oral dosage forms.

#### § 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications.* Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated

## § 520.1044b

swine for food for at least 3 days following treatment.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997; 71 FR 13542, Mar. 16, 2006]

### § 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications.* Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsors.* See Nos. 000061 and 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use.* In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations.* For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997; 78 FR 17596, Mar. 22, 2013]

### § 520.1044c Gentamicin sulfate powder.

(a) *Specifications.* Each gram of powder contains gentamicin sulfate equivalent to:

(1) 16.7, 66.7, or 333.3 milligrams (mg) gentamicin.

(2) 333.3 mg gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) No. 000061 for products described in paragraph (a)(1) of this section.

(2) Nos. 057561 and 061623 for product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water for 3 consecutive days as follows:

(i) For colibacillosis: Gentamicin sulfate equivalent to 25 mg of gentamicin per gallon of drinking water to provide

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0.5 mg per pound of body weight per day;

(ii) For swine dysentery: Gentamicin sulfate equivalent to 50 mg of gentamicin per gallon of drinking water to provide 1 mg per pound of body weight per day. Treatment may be repeated if dysentery recurs.

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water.

(4) *Withdrawal period.* 10 days.

[77 FR 4226, Jan. 27, 2012]

### § 520.1100 Griseofulvin.

(a) *Specifications*—(1) The powder complies with U.S.P. for griseofulvin, microsize.

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 061623 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount and indications for use*—(A) For equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of